DARCO

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510(k) Summary

K062103

Submitter Data: Darco International, Inc.
810 Memorial Blvd.
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OCT 25 2006

Contact: Mark S. Cooper

Date: July 21, 2006

Device Name: DARCO Force Compression Screw

Common Name: Bone Screw

Classification Name: Smooth or threaded metallic bone fixation fastener
(21 CFR 888.3040)

Legally Marketed Predicate Device: O.M.T. Scarf Screw (K042079)

Device Description: The DARCO Force Compression Screw is a self drilling, self tapping and self counter sinking 3.2mm hex drive cannulated screw with a reverse cutting nib designed into the thread pattern. The cannulated feature allows for the use of a drill guide for precise placement while the smooth shank between the threaded portions of the screw allows the bone surfaces to be compressed to facilitate healing. The screws are made of Ti 6-Al 4-V biocompatible titanium alloy and coated with an anodized finish.

Intended Use: The DARCO Force Compression Screw is for fixation and stabilization of fractures and non-unions of small bones and small bone arthrodeses including but not limited to intra-articular fractures of the tarsals, metatarsals, carpals and metacarpals, bunionectomies and osteotomies, and arthredeses of small joints (e.g. phalanges).

Technological Characteristics: The DARCO Force compression screw is designed with a self counter sinking and reverse cutting feature which the predicate device does not have. The DARCO screw is anodized while the predicate device has a CERID coating. These differences do not alter the safety, effectiveness, or intended use of the proposed device.

Performance Data: No clinical tests were used in the claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 2006

Darco International, Inc.
% Mr. Mark S. Cooper
Director of Regulatory Affairs
810 Memorial Boulevard
Huntington, West Virginia 25701

Re: K062103
Trade/Device Name: DARCO Force Compression Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: October 19, 2006
Received: October 20, 2006

Dear Mr. Cooper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buch MD
for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k)
Statement of Indications for Use

510(k) number (if known)	K062103
Device Name	DARCO Force Compression Screw
Indications for Use	The DARCO Force Titanium Compression Screw is to be used on indications that are common for currently marketed compression screws. The primary indication for use is the fixation and stabilization of the fractures and non-unions of small bones and small bone arthrodeses including but not limited to intra-articular fractures of the tarsals, metatarsal, carpals and metacarpals, bunionectomies and osteotomies, arthrodesis of small joints (e.g. phalanges).

Prescription Use XXX (Part 21 CFR 801 Subpart D) AND/OR Over the Counter Use _____ Part 21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE) Page 1 of 1

Barbara Buchman for MKM

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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